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APPENDIX F

Patient Solutions Inc.

MODEL 1200

510(k) Summary



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510(k) SUMMARY

Submitter's Name: Patient Solutions Inc.(PSI)

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Phone: (619) 679-3840

Contact: Tom Kane

Date of Summary: April 1, 1996

Name of Device: Model 1200 Ambulatory Infusion Pump

Legally Marketed Device to Which Substantially Equivalency Is Claimed:

Sabratek 6060 Homerun and Abbott Aim

Description of Device:

The PSI Model 1200 is a small portable ambulatory infusion pump intended for hospital, clinic and home care use. It uses dedicated disposables and related accessories.

Intended Use:

The PSI Model 1200 ambulatory infusion pump is a multifunction pump designed to manage a wide variety of intravenous fluid profiles.

Technological Characteristics

The PSI, Sabratek and Abbott ambulatory infusion pumps all have the same general design and incorporate similar technologies, materials, and components.

The primary function of the PSI Model 1200 is the same as the Sabratek 6060 and Abbott Aim, to administer fluids to a patient. The technological characteristics of the devices are the same and raise no new questions of safety and effectiveness. PSI concludes that the PSI Model 1200 is substantially equivalent to the Sabratek 6060 and Abbott Aim in providing infusion fluid therapy for the same clinical purposes that require the use of an ambulatory infusion pump.

262